PROFESSIONAL ORTHOPAEDIC ASSOCIATES

*Board Certified
Fellowship Trained
Orthopaedic Surgeons

Harry A. Bade III, MD, FACS"
Christopher **D. Johnson, MD, FACS***
Gordon D. Donald III, MD, FACS*
Brian M. Torpey, MD*
Gregg R. Foos, MD'
David R. Gentile, MD
Barry L. Swick, MD

Sports Medicine
Arthroscopic Surgery
Hand & Microsurgery
Spinal Surgery
Scoliosis Surgery
Shoulder Surgery
Knee Surgery
Foot and Ankle Surgery
Total Joint Replacement

Reply to:
776 Shrewsbury Avenue, Suite 201
Tinton Falls, New Jersey 07724
Phone (732) 530-4949
Fax **(732)** 530-3618
or (732) 530-3234

368 Lakehurst Road, Suite 203/206
Toms River, New Jersey 08753
Phone **(732)** 341-6777
Fax (732) 349-7722

203 Route 9 South
Marlboro, New Jersey 07726
Phone (732) **536-5410**
Fax (732) 536-5465

97N-4845

C56

December 3, 1999

Document Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 97N-484F

Dear Sirs:

I would just like to register with you my concern regarding the consideration of the FDA regulating allograft bone and allograft products as medical devices.

This is clearly overstepping the bounds of the FDA, as this is human graft material and not a medical device. Although allografts may come preliminarily machined for surgical use, they are not manufactured devices and may be readily intraoperatively modified by the surgeon such that they should not require any FDA consideration or regulation.

I strongly object to the FDA considering regulation of allograft material.

Thank you for your time and consideration.

Sincerely,

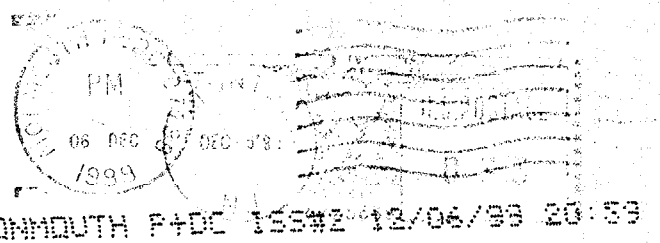
Gordon D. Donald III, M.D.

GDD:PTI

Dictated but not read to avoid further delay.

PROFESSIONAL
ORTHOPAEDIC
ASSOCIATES

776 Shrewsbury Avenue, Suite 201
Tinton Falls, New Jersey 07724



Document Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

20857-0001